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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,925	04/20/2004	Enrico Cappelletti	57637/1380	5906
35743 7590 09/26/2008 KRAMER LEVIN NAFTALIS & FRANKEL LLP INTELLECTUAL PROPERTY DEPARTMENT 1177 AVENUE OF THE AMERICAS NEW YORK, NY 10036				
EXAMINER JONES, DAMERON LEVEST				
ART UNIT 1618		PAPER NUMBER		
NOTIFICATION DATE 09/26/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

klpatent@kramerlevin.com

Office Action Summary**Application No.**

10/828,925

Applicant(s)

CAPPELLETI ET AL.

Examiner

D. L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/24/08 & 8/21/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51, 53-55, 57, 59, 61-70, 82, 84-86, 88, 90 and 107-109 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51, 53-55, 57, 59, 61-70, 82, 84-86, 88, 90, and 107-109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 6/24/08 wherein claims 1-50, 522, 56, 58, 60, 71-81, 83, 87, 89, and 91-106 were canceled and claims 51, 65-67, and 82 were amended. In addition, the Examiner acknowledges receipt of the request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/21/08 has been entered.

Note: Claims 51, 53-55, 57, 59, 61-70, 82, 84-86, 88, 90, and 107-109.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments and/or amendment filed 6/24/08 to the rejection of claims 51, 53-55, 57, 59, 61-70, 82, 84-86, 88, 90, and 107-109 made by the Examiner under 35 USC 112 and/or double patenting have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 Second Paragraph Rejections

The 112, second paragraph, rejections are WITHDRAWN because Applicant has amended the claims to overcome the rejections.

Double Patenting Rejections

I. The rejection of claims 51, 53-59, 61-70, 82, 84-86, 88, 90, and 107-109 on the ground of nonstatutory obviousness-type double patenting as being unpatentable

over claims 1-22 of U.S. Patent No. 7,226,577 is MAINTAINED for reasons of record in the office action mailed 10/9/07 and the advisory action mailed 8/1/08.

II. The provisional rejection of claims 51, 53-59, 61-70, 82, 84-86, 88, 90, and 107-109 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-87 of copending Application No. 10/542,202 is MAINTAINED for reasons of record in the office action mailed 10/9/07 and the advisory action mailed 8/1/08.

III. The provisional rejection of claims 51, 53-59, 61-70, 82, 84-86, 88, and 90 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 11/165,721 is MAINTAINED for reasons of record in the office action mailed 10/9/07 and the advisory action mailed 8/1/08.

IV. The provisional rejection of claims 51, 53-59, 61-70, 82, 84-86, 88, and 90 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-57 of copending Application No. 11/352,156 is MAINTAINED for reasons of record in the office action mailed 10/9/07 and the advisory action mailed 8/1/08.

V. The provisional rejection of claims 51, 53-59, 61-70, 82, 84-86, 88, and 90 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 69-91 of copending Application No. 11/467,237 is MAINTAINED for reasons of record in the office action mailed 10/9/07 and the advisory action mailed 8/1/08.

VI. The provisional rejection of claims 51, 53-59, 61-70, 82, 84-86, 88, and 90 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 69-91 of copending Application No. 11/467,301 is MAINTAINED for reasons of record in the office action mailed 10/9/07 and the advisory action mailed 8/1/08.

VII. The provisional rejection of claims 51, 53-59, 61-70, 82, 84-86, 88, and 90 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-17, 20-23, 26, 29, 30, 35, 36, 39-42, 50, 60, 61, 64-67, 74, 80, 81, and 84-87 of copending Application No. 10/566,112 is MAINTAINED for reasons of record in the office action mailed 10/9/07 and the advisory action mailed 8/1/08.

Note: It is duly noted that Applicant has requested that the double patenting and provisional double patenting rejections be held in abeyance until allowable subject matter is indicated or withdrawn as set forth in the remarks filed 6/24/08. It should be noted that none of the double patenting rejections are withdrawn as disclosed in the advisory action mailed 8/1/08.

NEW GROUNDS OF REJECTIONS

112 First Paragraph Rejection (Written Description)

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 51, 53-55, 57, 59, 61-70, 82, 84, 86, 88, 90, 108, and 109 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description

requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In particular, written description is lacking because neither the claims nor the disclosure set forth what R1 group (than -NH₂, -SH, and -COOH, see page 56, paragraph [00170] of the specification) can be used as a site for covalently linking M and the R2 group that is used for covalent coupling to the N-terminal NH₂ group of G (other than -COOH, see page 56, paragraph [00170] of the specification). Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention as it relates to the variables R1 and R2. What the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for achieving a certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description of the variables R1 and R2 is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed.

Thus, the written description requirement is lacking in the instant invention since the various terms as set forth above are not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

112 First Paragraph Rejection (Scope of Enablement)

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 51, 53-55, 57, 59, 61-70, 82, 84, 86, 88, 90, 108, and 109 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the R1 groups -NH₃, -SH, and -COOH and the R2 group -COOH, does not reasonably

provide enablement for all R1 groups that may be used as a site for covalently linking M and all R2 groups that may be used for covalently coupling the N-terminal NH₂ group of G. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The instant invention is directed to compounds and methods thereof as set forth in independent claims 51, 82, 85, and 107. The compounds are encompassed by the formula M-N-O-P-G (definitions provided in independent claims 51 and 82).

(2) State of the prior art

The state of the prior art is such that it neither anticipates nor renders obvious the instant invention. As a result, in order to fully understand what is being claimed, the

variables R1 and R2 must be defined such that one can clearly ascertain what the metes and bounds of the invention involve.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. There is no evidence of record which would enable the skilled artisan in the identification of all possible groups encompassed by R1 and R2 which are applicable to the instant invention.

(4) Level of predictability in the art

The art pertaining to compounds encompassed by the formula M-N-O-P-G is highly unpredictable since the attachment of the various components depends on the peptide selected, the metal/chelator used, and the presence or absence of other amino acids selected for N-O-P. Hence, determining the various R1 and R2 groups compatible with the instant invention requires various experimental procedures and without guidance that is applicable to all compounds encompassed by M-N-O-P-G, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

There is no evidence of record which would enable the skilled artisan in the identification of R1 and R2 groups other than those specifically disclosed by Applicant in the specification (page 56, paragraph [00170]). Applicant's limited guidance does not enable the public to prepare such a numerous amount of R1 and R2 groups for the unlimited number of possible peptides and amino acid combinations (N-O-P) encompassed by the claim.

(6) Existence of working examples

The specification, page 56, paragraph [00170] discloses that R1 may be -NH₂, -SH, or -COOH and R2 may be -COOH. Thus, because the instant invention is novel and Applicant's limited 'working examples' do not set forth other possible R1 and R2 values compatible with the instant invention, the public would lack the necessary tools to prepare such a numerous amount compounds for the various uses.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible R1 and R2 values known to exist.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 Second Paragraph Rejection

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 51, 53-55, 57, 59, 61-70, 82, 84, 86, 88, 90, 108, and 109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly

point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because it is unclear what groups are encompassed by the variables R1 and R2 as set forth in independent claims 51 (lines 35-37) and 82 (lines 32-34). Thus, since the scope of the independent claims cannot be ascertained, all claims depending thereon are also vague and indefinite.

COMMENTS/NOTES

9. The search was expanded over the full scope of the instant invention. In particular, the claims are distinguished over the prior art of record because the prior art of record neither anticipates nor renders obvious the inventions as set forth in independent claims 51, 82, and 107.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/
Primary Examiner
Art Unit 1618

September 19, 2008